

### **DETAILED ACTION**

1. Claims 19-36 are pending and at issue.

#### ***Priority***

2. It is noted that certified English translations of priority documents have not been provided.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

#### ***Specification***

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect that a polymer coated adsorbent is used in the claimed methods .
4. The use of the trademarks TRITON and TWEEN have been noted in this application. They and any other trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant is advised to scan the entire application to ensure trademark usage in all the places where it appears in the application is in compliance with the current office guidelines.

### ***Claim Objections***

5. Claim 29 is objected to for improper identification of the trademarks TRITON and TWEEN. They and any other trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

6. Claim 19 objected to because of the following informalities: improper grammar and inconsistent punctuation in the series given at the end of the claims. Appropriate correction is required.

### ***Claim Interpretation***

7. Owing to the claim objection, claim 19 is interpreted as every element of the series having equal choice. The claim is additionally difficult to interpret as acrylamides, methylacrylmides, and acrylic esters are not acids. The claim is thus interpreted as follows.

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9. (New) A method for the accumulation and stabilization of DNA-containing components, characterized in that:

DNA-containing sample material is partially lysed in a lysis-binding buffer system comprising at least one lysis reagent and at least one solid adsorbent to release DNA-containing components, and

the DNA-containing components are bound to the adsorbent, the surface of the adsorbent being functionalized with polymers consisting of:

(i) a carrier polymer and/or acid component(s) of polymerizable acids,  
or (ii) derivatives of polymerizable acids selected from acrylic acids,  
or (iii) methacrylic acids,  
or (iv) acrylamides,  
or (v) methacrylamides,  
or (vi) acrylic esters,  
or ~~from~~ (vii) copolymers of carrier polymer and an acid component, the latter being selected from sulfonic acids, phosphonic acids or carboxylic acids.

A DNA-containing component is interpreted as anything containing DNA, including DNA itself. Also, “lysed” and “bound” are interpreted as active steps, see the following section.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 19-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 19-36 are indefinite and vague because the claims are written in the passive tense. Method claims should recite positive, active process steps (see *Ex parte Erlich* 3 USPQ 2d 1011). This rejection may be overcome by amending the claims to recite the active tense, e.g. in claim 19 to recite: "partially lysing the DNA-containing sample...".

11. Claim 29 contains the trademark/trade names TRITON, TWEEN, and NP-40 (NONIDET™ P 40). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe non-ionic detergents and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21, 25, 26, 33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Su (United States Patent 5,804,684 issued September 8, 1998).

Regarding claim 19, Su et al. teach methods for the accumulation and stabilization of DNA-containing components (entire patent, especially the Abstract), characterized in that DNA-containing sample material is partially lysed by proteolysis in a lysis-binding buffer system comprising at least one lysis reagent which is a proteolytic enzyme (see paragraph 2) and at least one solid adsorbent which is matrix comprising a solid hydrophilic organic polymer (see Abstract, column 4 line 6) to release DNA-containing components (see claim 19), and the DNA-containing components are bound to the adsorbent/matrix (see claim 1), the surface of the adsorbent being functionalized with polymers consisting of: a hydrophilic organic polymer (see Abstract) which can be polyacrylamide (see claim 10a) which is a type of acrylamide; or a carrier polymer having a carboxylic acid (COOH, see column 3 line 31).

Regarding claim 20, Su et al. teach that contaminants are removed (see column 2 lines 35-58).

Regarding claim 21, Su et al. teach that the adsorbent/matrix is added after lysis by teaching the sample is initially lysed by proteolysis (see column 3 lines 51-56).

Regarding claim 25, Su et al. teach that polymer particles are prepared and thus inherently teach the adsorbent/matrix consists of organic material to which the polymers are bound, as the polymers which are organic material are bound to other polymers (see column 3 line 24-49 and see polyacrylamide gel particles in claim 10a).

Regarding claim 26, Su et al. teach microparticles with diameters of 5-500  $\mu\text{m}$  which overlaps the range of 1-100  $\mu\text{m}$  are used as the adsorbent/matrix (see column 7 lines 18-25).

Regarding claim 33, Su et al. teach that biological samples are used as the DNA-containing material (see column 2 line 35-47).

Regarding claim 35, Su et al. teach that DNA-containing components are washed away with washing solution which is an aqueous salt solution (see column 10 lines 7-9).

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Su as applied to claim 35 above.

Su et al. teach as noted above.

Regarding claim 36, Su et al. teaches sodium chloride at 0.2 M (see column 10 lines 7-9) and teaches using calcium chloride to precipitate nucleic acid aggregate in order to increase the formation of aggregates which bind to the matrix (see column 9 lines 17-34), but does not specifically teach calcium chloride from 0.01 to 3.0 M.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the washing solution of Su by substituting calcium chloride for sodium chloride as suggested by Su with a reasonable expectation of success. The motivation to do so is provided by Su who teaches that salts in general can be used to elute nucleic acids and that calcium chloride enhances recovery of nucleic acids (see column 9 lines 17-34). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

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16. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su as applied to claim 19 above, and further in view of Sutton et al. (United States Patent 5,380,489 issued January 10, 1995).

Su teaches as noted above.

Regarding claims 22-24, Su teaches polymers and copolymers with acid groups but does not specifically teach styrene sulfonic acid as the acid component.

Regarding claims 22-24, Sutton et al. teaches a first polymer and a second polymer which is a copolymer and teaches that copolymer can be from 0 to about 45 weight percent and which can be styrene sulfonic acid (see column 8 line 46 and column 9 line 15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the polymers of Su by using styrene sulfonic acids as suggested by Sutton et al. with a reasonable expectation of success. The motivation to do so is provided by Su who teach acid polymers for binding nucleic acids including DNA and the teaching of Sutton et al. who also teach that acid polymers including those specifically of styrene sulfonic acid stably bind nucleic acids for use in diagnostics (see column 1 lines 7-30). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

17. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Su as applied to claim 19 above, and further in view of Arnold et al. (United States Patent Application 20020193457 published December 19, 2002).



Su teaches as noted above.

Regarding claim 25, Su teaches modifying polymers and the surfaces of matrices but does not specifically teach magnetic particles.

Regarding claim 27, Arnold et al. teach carboxyl-coated magnetic particles (see paragraph 0008).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Su by using acid polymer coated magnetic particles as suggested by Arnold et al. with a reasonable expectation of success. The motivation to do so is provided by Arnold et al. who teach nucleic acids bound to acid polymer coated magnetic particles are easily separated from contaminants by magnetic separation (see 0010). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

18. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su as applied to claim 19 above, and further in view of Grattard et al. (1993).

Su teaches as noted above.

Regarding claims 28-32, Su teaches lysis buffers but does not specifically teach a lysis buffer comprising a TRITON non-ionic detergent.

Regarding claims 28-32, Grattard et al. teach a lysis reagent which is STET buffer comprising 50 mM Tris-HCl, 50 mM EDTA, 233 mM saccharose, 5% Triton X-100 [pH 8] containing 50 µg of lysostaphin from Sigma Chemical Co., La Verpilliere, France (see 2<sup>nd</sup> sentence of 2<sup>nd</sup> paragraph on p. 813).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Su by using the lysis reagent as suggested by Grattard et al. with a reasonable expectation of success. The motivation to do so is provided by Grattard et al. who teach that plasmid DNA are recovered from bacteria with the lysis buffer and the teaching of Su that lysed cells improve the purification of DNA. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

19. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Su as applied to claim 19 above, and further in view of Kausch et al. (United States Patent 5,508,164 issued April 16, 1996).

Su teaches as noted above.

Regarding claims 34, Su teaches binding/accumulating plasmids but does not specifically teach binding of cell organelles.

Regarding claim 34, Kausch et al. teach binding/accumulating cell organelles including chloroplast on particles (see claim 2) which can be polymer beads (see claim 14).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Su by binding cellular components as suggested by Kausch et al. with a reasonable expectation of success. The motivation to do so is provided by Kausch et al. who teach that the methods of particle binding of cell organelles: “. . . presents numerous advantages in terms of time,

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resolution, purity, and preservation of the structure of the biological material during isolation and separation” (see Abstract). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Conclusion***

20. No claim is free of the prior art.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 7:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples

/M. S./

Examiner, Art Unit 1637

October 17, 2008

/Kenneth R Horlick/

Primary Examiner, Art Unit 1637